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Contact A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0102]

Referral of KEMSTRO (Baclofen) and DROXIA (Hydroxyurea) for the Conduct of Pediatric Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the referral of KEMSTRO (baclofen) and DROXIA (hydroxyurea) to the Foundation for the National Institutes of Health (the Foundation) for the conduct of pediatric studies. FDA referred KEMSTRO (baclofen) and DROXIA (hydroxyurea) to the Foundation on September 1, 2004, and October 20, 2004, respectively. FDA is publishing this notice of the referrals in accordance with the Best Pharmaceuticals for Children Act (BCPA).

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written requests for the conduct of pediatric studies for KEMSTRO (baclofen) and DROXIA (hydroxyurea). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive program described in

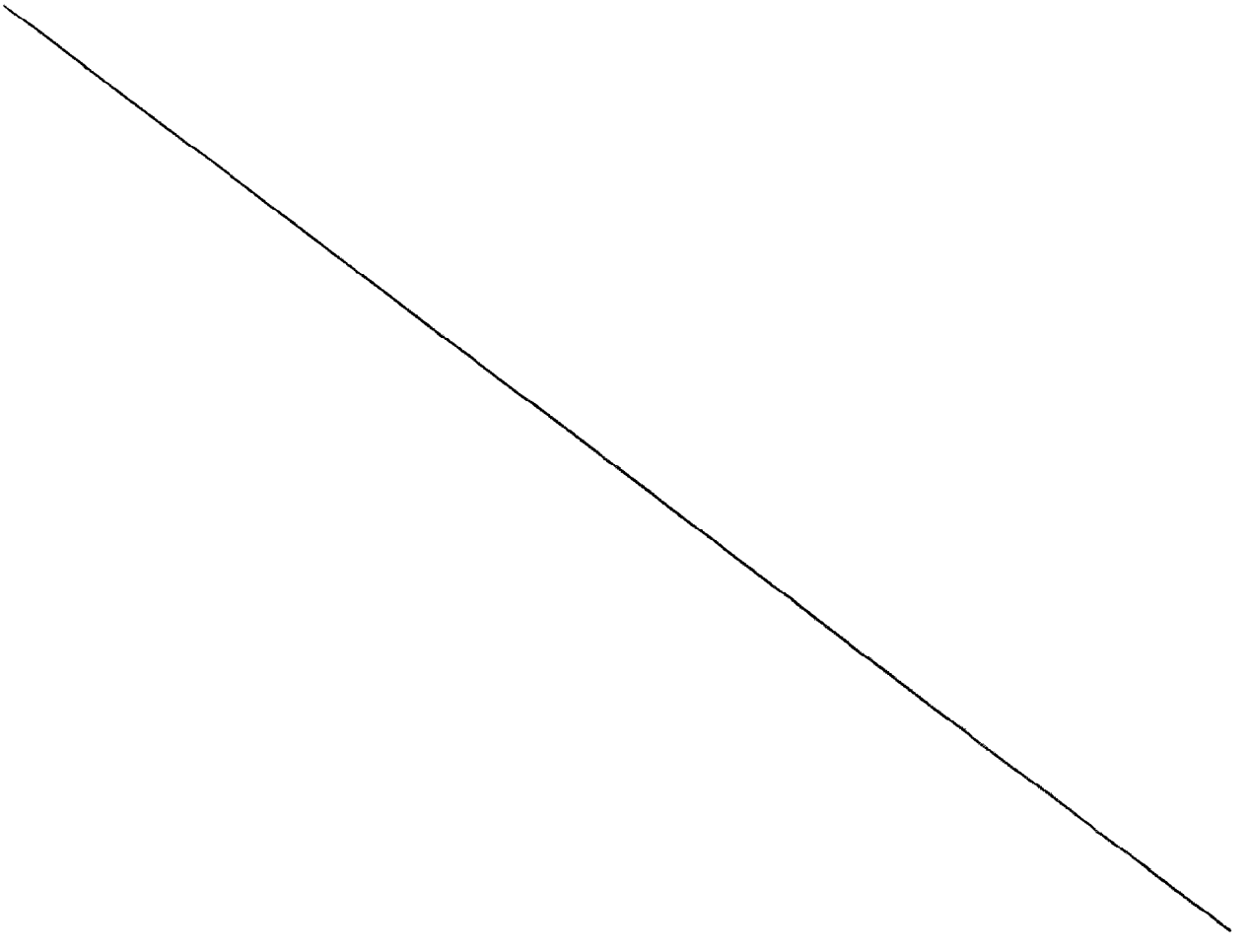
section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the manufacturer, and indications to be studied under the referrals (21 U.S.C. 355a(d)(4)(B)(ii)).

In accordance with section 4 of the BPCA, FDA is announcing that it has referred to the Foundation the written requests for pediatric studies for KEMSTRO (baclofen) and DROXIA (hydroxyurea). On April 30, 2004, FDA issued a written request for pediatric studies to Schwarz Pharma, Inc., the holder of approved applications for KEMSTRO (baclofen) that have market exclusivity. The studies described in the written request were for the treatment

of spasticity in the pediatric population. Schwarz Pharma, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of KEMSTRO (baclofen) in the pediatric population.

On March 29, 2004, FDA issued a written request for pediatric studies to Bristol-Myers Squibb Co., the holder of approved applications for DROXIA (hydroxyurea) that have market exclusivity. The studies described in the written request were for the treatment of sickle cell disease in the pediatric population. Bristol-Myers Squibb Co. declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of DROXIA (hydroxyruea) in the pediatric population.



Consistent with the provisions of the BPCA, FDA referred to the Foundation the written requests for the conduct of the pediatric studies for KEMSTRO (baclofen) on September 1, 2004, and DROXIA (hydroxyurea) on October 20, 2004.

Dated: 3/22/05
March 22, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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